From: Kevin Nicholson <KNicholson@NACDS.org>
To: Andy Becker; Anthony Provenzano; Brad Tice (brad.tice@cardinalhealth.com); Bryan Dunwoody; Chris Dimos; Chuck Reed; Dale Masten; Dempsey, Donald A.; Ed.Kaleta@walgreens.com; Fred Ottolino; Gates, Rick; Gayle Shields; George Chapman; Gregory, Steven; Jeff Loesch; Jeffrey Mondelli (jeffrey.mondelli@wakefern.com); Jennifer Speares; John Carlo; Karen Mankowski; Kristin Williams, R.Ph.; Lynne Fruth; Mark Polli; Mike Duteau; Mike Podgurski; Read, Douglas; Robert Swart; Steve McCann; Susanne Hiland; Tim Weippert; Davis, Thomas G.; Vic Curtis; Yong Choe
CC: Steve Anderson; Kathleen Jaeger; Don Bell; Dave Fitzsimmons; Chris Krese; Govt Affairs and Public Policy
Sent: 10/11/2017 4:53:21 PM
Subject: [EXTERNAL] NACDS Policy Council Follow Up
Attachments: 7 day supply model state legislation_Oct6.docx; 2018 NACDS Policy Issues Survey.doc; 2018 NACDS Policy Issues Survey.pdf; Centers for Medicare & Medicaid Services_ Innovation Center New Direction.pdf; Draft Model State Drug Disposal Legislation Oct 6 2017 (1).docx; Draft_Federal_Model_Mandatory_Eprescribing_All_Drugs_Oct 11 2017.docx; NACDS Policy Council Report_v3 Final.pptx; October Policy Council Powerpoint.pptx; Pharmacist Immunization Model Language.docx

Dear NACDS Policy Council Members:

Thank you for your participation in today's Policy Council meeting. We had a very productive meeting and enjoyed seeing everyone. We will NOT have a Policy Council call this week.

Follow-up action items are below. The presentation slides from the meeting are attached. Cathy Graeff's slides are also attached.

Action items for Policy Council Members

- **2018 Policy Issues Survey** – The 2018 NACDS Policy Council Issues Survey is attached in both Word and PDF formats. **Please complete the online survey tool by October 20 at 12 noon EDT. Here is the link to the online survey:** http://survey.nacds.org/Survey.aspx?s=728c2c92188249b089a35c3c612c6c7d.

  Please note that the survey is being sent to each Policy Council member only.

- **Model Legislation – Please provide all feedback by COB, October 20**. The draft model legislative proposals are attached.
  - **Drug Disposal Model State Legislation**- Please review internally within you company, especially any concerns about providing drug return/disposal envelopes/items, as would be required in the model bill. NACDS will engage with manufacturers about the mandate that they fund the drug return/disposal envelopes/items.
  - **Model State Legislation – Seven Day Supply Limits for Opioid Prescriptions for Acute Pain:** Please review.
  - **Model Federal E-Prescribing Bill –** We amended the legislation based on today's discussion. Edits are redlined. Please review for any concerns. The draft legislation is based on existing federal legislation to mandate EPCS that NACDS supports. This legislation would expand the existing federal bill to mandate e-prescribing for all prescription medications.

- **Pharmacist Workload Research – Please provide your recommendation by COB, October 20** whether NACDS should pursue (1) the proposed research from UW-Madison, (2) Avalere, or (3) both. NACDS recommends with pursuing both. See pp. 15-18 of the attached "October Policy Council Meeting Powerpoint" as a refresher on the proposals.

- **CMMI RFI –** Please see the attached RFI. Please provide feedback on how **NACDS should respond to the RFI by COB, October 20**.

- **Specialty Pharmacy in Medicaid –** Please let us know if you are willing to review the specialty product list for use in the upcoming Cost of Dispensing Survey. There is no immediate deadline for this request.

- **Policy Council Executive Committee-** Please provide your nominee(s) for Policy Council Executive Committee for 2018. We have one open position: At-Large Member. **Please respond by COB, November 1.**

Action items for NACDS Staff

- **Drug Disposal Model State Legislation-** NACDS will engage with manufacturers about the mandate that they fund the drug return/disposal envelopes/items.
- **DEA and Transferring Unfilled Prescriptions-** NACDS will send the DEA letter to NABP and ask NABP to communicate it to the state boards of pharmacy. Also, NACDS will ask DEA to clarify whether unfilled EPCS can be transferred in formats other than electronic.
- **DEA Suspicious Order Monitoring and the *Masters* Decision-** NACDS will draft a letter to DEA asking for clarifying/guidance on suspicious order monitoring in light of the *Masters* decision. We will provide the draft letter to the Policy Council for review before sending to DEA.
- **HHS Draft Strategic Plan –** NACDS will send a draft letter for you to review by COB, Friday, October 13.

Important Information

- **Pharmacist Immunization State Model Language –** The Policy Council approved the attached draft model language.

Please let us know any questions or comments.

Thanks again, Kevin

Kevin N. Nicholson, R.Ph., J.D.
Vice President, Public Policy and Regulatory Affairs
knicholson@nacds.org
P: (703) 837.4183
Assistant: Elliott Moore, emoore@nacds.org

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd. Suite 200 Arlington, VA 22209

www.nacds.org
www.facebook.com/NACDS.org
www.twitter.com/@NACDS

NACDS

NACDS Policy Council Meeting

NACDS Headquarters

Arlington, VA

October 11, 2017

Pharmacies. The face of neighborhood healthcare.

NACDS

Introductions & Review of Antitrust Statement

Pharmacies. The face of neighborhood healthcare.

NACDS

Discussion Items

Pharmacies. The face of neighborhood healthcare.

NACDS

Combating Opioid Abuse

Pharmacies. The face of neighborhood healthcare.

NACDS

Combating Opioid Abuse

- Model Legislation
  - State Initial Fill Limit
  - State Drug Disposal
  - Federal Electronic Prescribing

Pharmacies. The face of neighborhood healthcare.

NACDS

NACDS DEA Best Practices Forum

Pharmacies. The face of neighborhood healthcare.

NACDS

DEA and Transferring Unfilled Prescriptions

Pharmacies. The face of neighborhood healthcare.

NACDS

DEA Suspicious Order Monitoring and the *Masters* Decision

Pharmacies. The face of neighborhood healthcare.

NACDS

Pharmacist Workload Research

Pharmacies. The face of neighborhood healthcare.

NACDS

Pharmacist Workload

- NACDS Position
- Grasha Research
- Current workload issues in the states
- Research options to support future advocacy

Pharmacies. The face of neighborhood healthcare.

NACDS

NACDS Position

- Advocate against regulatory restrictions, dispensing limits, and fines to address issues related to pharmacist errors.
- Promote the establishment of quality assurance programs so that pharmacies have a way to resolve issues without legal consequences.

Pharmacies. The face of neighborhood healthcare.

NACDS

Grasha Research

- NACDS previously funded research on errors with Tony Grasha, a psychologist with the University of Cincinnati, in 2001.
- Dr. Grasha's work focused on the areas of human systems functioning including human error and performance, team building, conflict management, interpersonal communication, problem solving and decision making, and stress management within organizations.
- The research funded by NACDS concluded that human errors are part of a complex system of factors including tasks, intrapersonal, interpersonal, environment, organizational, and extra-organizational and that a pharmacist's workload cannot be used as the defining factor for the cause of errors.

Pharmacies. The face of neighborhood healthcare.

NACDS

Issues in the States

- **Enhanced Technician Duties**: May affect NACDS pharmacy technician efforts. If pharmacist workload is overregulated, seeking enhanced technician duties will be difficult.
- **Organized Labor**: Pushing for more regulation on pharmacist workload in some states.
- **Technology**: Perception that technology and technicians will reduce demand for pharmacists and increase workload.

Pharmacies. The face of neighborhood healthcare.

NACDS

Issues in the States

- **New Hampshire**:
  - Mandating bathroom breaks
  - Limiting number of prescriptions filled per hour
  - Pharmacist cannot administer flu shot without second pharmacist behind counter
  - PIC must take an exam to prove he/she knows the law
- **Vermont**: Limit number of prescriptions filled to 8 per hour
- **Connecticut**: Quotas for filling prescriptions and administering vaccines used to determine bonuses
- **Minnesota**: Mandating breaks for pharmacists
- **Oregon**: PIC responsible for all staffing and operations in the pharmacy

Pharmacies. The face of neighborhood healthcare.

NACDS

Research Options to Support Future Advocacy

- **Option 1**: Dr. Michelle Chui, University of Wisconsin
- **Option 2**: Avalere
- **Option 3**: Both projects

Pharmacies. The face of neighborhood healthcare.

NACDS

Option 1: UW-Madison

- Proposal to summarize current research on factors that increase or reduce the likelihood of errors and factors that improve the quality of care. The white paper will also address different approaches to improving quality and/or reducing errors. Pharmacist workload will be conceptualized as a ratio of demands to resources.
- The paper will:
  - Describe what pharmacists need to do in the workplace from the lens of a human factors systems engineer.
  - Describe human cognitive limitations and how those limitations can lead to errors by, in part, providing evidence from other high risk industries such as nuclear power and aviation.
  - Then, from a systems approach, describe current approaches to reducing errors and improving quality, including approaches that have been used in other high-risk industries that may be implemented in retail pharmacies.
- This white paper is estimated to be 10-12 pages.

Pharmacies. The face of neighborhood healthcare.

Option 2: Avalere

- Proposes to conduct primary and secondary research to develop a 10-page, Avalere-branded white paper to describe the operational aspects of the practice of pharmacy within the community pharmacy setting, with a particular focus on resources that are leveraged to ensure and advance patient safety and quality of care with respect to medications. The paper will include:
  - A literature review of how pharmacy practice has integrated processes, technology, and systems engineering to optimize patient safety in medication dispensing and patient education into effective use.
  - An overview of current quality of care metrics that are utilized within the community pharmacy setting and how measurement and outcomes have evolved over time.
  - Two case studies as examples of innovation in patient safety based on interviews with selected NACDS members to provide real-world examples of how technology/systems engineering has been leveraged in the goal of optimizing patient safety and quality of patient care.
- NACDS will provide feedback on the draft white paper prior to finalizing. However, Avalere will maintain editorial control.

Pharmacies. The face of neighborhood healthcare.

NACDS

Additional Research from Purdue University

- NACDS approached Purdue University to submit a proposal for further research on pharmacist workload issues.
- However, Purdue is currently doing research for APhA on a similar issue, in the form of a literature review.
- The results of this research will be public and may be used by NACDS for advocacy purposes.

Pharmacies. The face of neighborhood healthcare.

NACDS

2018 Policy Issues Survey

Pharmacies. The face of neighborhood healthcare.

NACDS

Proposed Change to Survey

- **Original:**
  - **<u>PBM Issues, Specialty Pharmacy, and Medicaid Managed Care</u>**
    - NACDS has developed model legislation for the regulation of PBM practices. The NACDS PBM Task Force continues to review and modify this model legislation. However, potential issues in this category include DIR Fees, PBM audits of pharmacies, PBM pricing issues such as MAC and generic predictability, pharmacy network issues, transparency between PBMs and payors, PBM treatment of patient data, the ability to provide 90-day supplies by retail pharmacies, and pharmacy discount cards. This issue area also includes the shift to Medicaid Managed Care, medication synchronization, and concerns about patient access to medications that payers may define as "specialty."

Pharmacies. The face of neighborhood healthcare.

Proposed Change to Survey

- **Proposed Change:**
  - **Medicaid Managed Care**
    - As Medicaid is increasingly shifting to Managed Care, NACDS plays a role in monitoring states currently moving to managed care including review of RFPs for inclusion of pharmacy-friendly terms such as minimum reimbursement or reimbursement tied to FFS rates. Additionally, in states with already established Managed Care programs, NACDS will work with members to identify approaches to improve the current operating climate and facilitate interactions with state Medicaid agencies where appropriate.
  - **PBM Issues and Specialty Pharmacy**
    - NACDS has developed model legislation for the regulation of PBM practices. The NACDS PBM Task Force continues to review and modify this model legislation. However, potential issues in this category include DIR Fees, PBM audits of pharmacies, PBM pricing issues such as MAC and generic predictability, pharmacy network issues, transparency between PBMs and payors, PBM treatment of patient data, the ability to provide 90-day supplies by retail pharmacies, and pharmacy discount cards. This issue area also includes the medication synchronization and concerns about patient access to medications that payers may define as "specialty."

Pharmacies. The face of neighborhood healthcare.

NACDS

2018 State Tiering

Pharmacies. The face of neighborhood healthcare.

NACDS

2018 Proposed Tiers

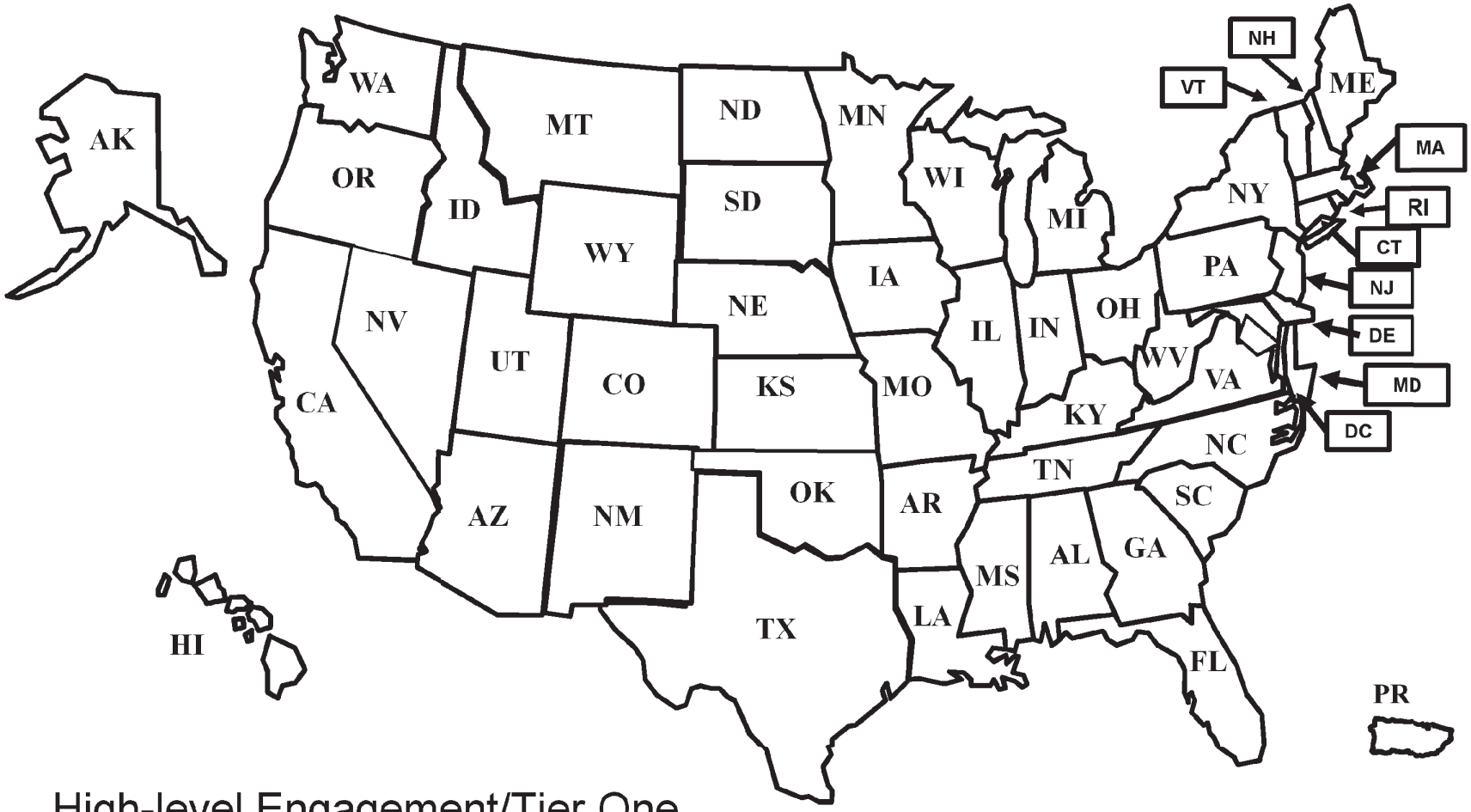
- **High-level Engagement/Tier One:**
  - **Arizona**, California, Colorado, Florida, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Washington, and Wisconsin
- **Collaborative Approach/Tier Two:**
  - Alabama, Alaska, Arkansas, Connecticut, Delaware, Georgia, Indiana, Idaho, Kentucky, Maine, Mississippi, Missouri, Montana, Nebraska, Nevada, New Mexico, Rhode Island, South Dakota, Utah, Vermont, Virginia, West Virginia, and Wyoming
- **Monitoring Approach/Tier Three:**
  - District of Columbia, Hawaii, Illinois, North Dakota, and Puerto Rico

Pharmacies. The face of neighborhood healthcare.

Note: Bold/Underline denotes a change

NACDS

2018 Proposed Tiers



High-level Engagement/Tier One
Collaborative Approach/Tier Two
Monitoring Approach/Tier Three

Pharmacies. The face of neighborhood healthcare.

NACDS

Pharmacist Immunization State Model Language

Pharmacies. The face of neighborhood healthcare.

NACDS

Guest Speaker: John Coster

Pharmacies. The face of neighborhood healthcare.

NACDS

Guest Speaker: Cathy Graeff

Pharmacies. The face of neighborhood healthcare.

NACDS

Status Updates

Pharmacies. The face of neighborhood healthcare.

NACDS

Federal Government Affairs

Pharmacies. The face of neighborhood healthcare.

NACDS

Federal Issue Update

- Provider Status
- Affordable Care Act Reform
- TRICARE Acquisition Cost Parity for Retail Pharmacy
- DIR Fees
- Electronic Prescribing of Controlled Substances

Pharmacies. The face of neighborhood healthcare.

NACDS

Provider Status

- H.R. 592/S. 109, the Pharmacy and Medically Underserved Areas Enhancement Act
  - 226 cosponsors in House
  - 45 cosponsors in Senate
- Recognize Pharmacists as Providers in Medicare
  - Reimbursed at 85% of the Physician Fee Schedule
  - Services Based on State Scope of Practice
- Coordinating advocacy and proposing options to reduce the cost of the bill with the Patient Access to Pharmacists' Care Coalition (PAPCC)
  - HPSA only
  - Delay Implementation
- Legislative Vehicles
  - Children's Health Insurance Program Reauthorization (program authorization expired on September 30)

Pharmacies. The face of neighborhood healthcare.

NACDS

Affordable Care Act Reform

- Advocacy Focus
  - Maintain Pharmacy Services in Medicaid
  - Preserve AMP-based FUL Provisions from ACA
- Strategy
  - Educate leading Members of Congress about policies that could threaten access, cost, and quality
  - Seek opportunities to expand pharmacy services
- Status
  - FY2017 budget reconciliation window closed September 30
  - Still possible that Senate moves forward with a narrow market stabilization bill – Alexander/Murray
  - Next budget could provide yet another opportunity for reform to be considered under reconciliation

Pharmacies. The face of neighborhood healthcare.

NACDS

TRICARE

- Pilot Program for Prescription Drug Acquisition Cost Parity in TRICARE (2017 NDAA)
  - Secretary has discretion to implement
  - FY2017 authorization expired October 1, 2017
  - Savings through lower drug acquisition costs and administrative costs for DoD – $19 million/year
- FY2018 NDAA
  - House bill includes 1-year extension of the pilot program and no prescription copay increases
  - Senate bill silent on pilot program and includes Administration-proposed copay increases

Pharmacies. The face of neighborhood healthcare.

NACDS

DIR Advocacy

- NACDS worked with members in the fall of 2016 to update DIR position
  - Seeks transparency and consistency in the use of fees, including DIR fees
  - Urge CMS to issue guidance for consistent terminology and disclosures on how fees are defined, how they will be calculated, the timing for fee collection, and how fees will be reported
- January 19 CMS Fact Sheet
- 28 House members signed Marino-Loebsack letter to HHS calling for guidance
- 11 Senators signed on to Grassley-Heitkamp letter to HHS calling for guidance
- NACDS continuing advocacy in Congress, at HHS, and with White House officials

Pharmacies. The face of neighborhood healthcare.

NACDS

EPCS in Medicare Part D

- H.R. 3528 – Every Prescription Conveyed Securely Act introduced by Rep. Katherine Clark (D-MA) and Rep. Markwayne Mullin (R-OK)
- Controlled substances in Part D must be eRx
- Includes all NACDS requested exceptions:
  - Prescriber and dispenser same
  - Constraints of SCRIPT
  - 1-year waiver: economic hardship; technological limitations
  - Impractical with adverse impact
  - Non-patient specific prescription
  - Research protocol
  - REMS with ETASU
- Pharmacy liability protections
- HHS enforcement authority

Pharmacies. The face of neighborhood healthcare.

NACDS

State Government Affairs

Pharmacies. The face of neighborhood healthcare.

NACDS

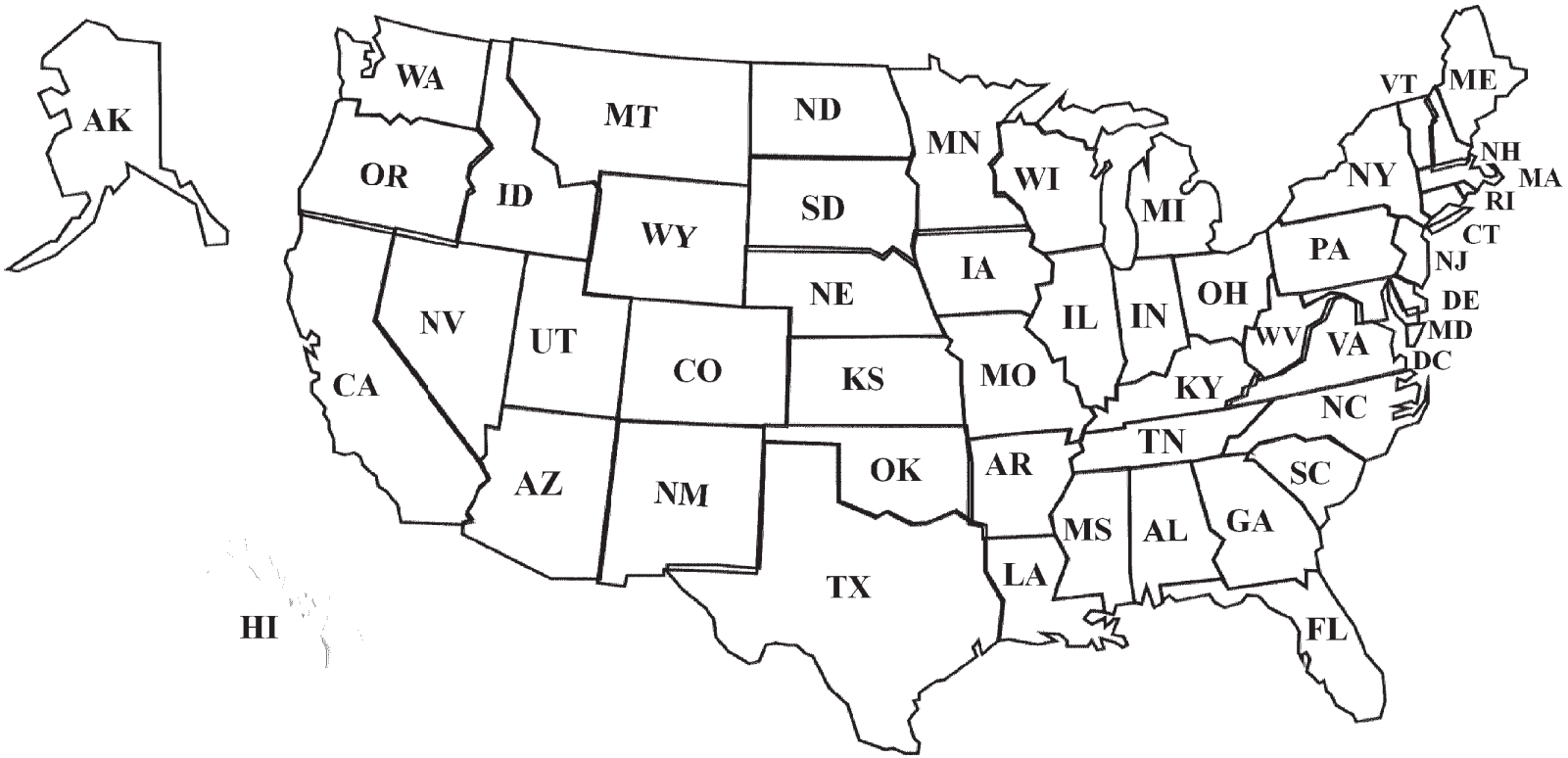
Medicaid Update

- Covered Outpatient Drugs Final Rule
  - Cost-based reimbursement
    - Compliance Date: April 1, 2017
    - SPA Submission Date: June 30, 2017

Pharmacies. The face of neighborhood healthcare.

NACDS

State Overview



- AAC/NADAC
- Managed Care Rx
- SPA Only
- Legislation and/or Regulation

Pharmacies. The face of neighborhood healthcare.

NACDS

HHS Update

Pharmacies. The face of neighborhood healthcare.

NACDS

HHS Update – CMMI RFI

- Innovation Center released Request for Information on September 20, 2017
- Purpose of the RFI is to seek:

  feedback on a new direction to promote patient-centered care and test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes.

Pharmacies. The face of neighborhood healthcare.

NACDS

HHS Update – CMMI RFI

- Comments due to Innovation Center by November 20, 2017. Potential areas for comment include:
  - Expanded Opportunities for Participation in Advanced APMs
  - Consumer Directed Care & Market-Based Innovation Models
  - Prescription Drug Models
  - MA Innovation Models
  - State-Based and Local Innovation Models
  - Program Integrity

Pharmacies. The face of neighborhood healthcare.

NACDS

HHS Update – Strategic Plan

- HHS updates its strategic plan every 4 years. Comments due October 26, 2017.
- Strategic Plan describes the Department's plans to address "complex multifaceted, and evolving health and human services issues."
- Objectives for potential comments:
  - *Objective 1.1: Promote affordable healthcare, while balancing spending on premiums, deductibles, and out-of-pocket costs.* (Medicare Fees)

Pharmacies. The face of neighborhood healthcare.

NACDS

HHS Update – Strategic Plan

- Objectives for potential comments (cont.):
  - *Objectives 1.3 and 1.4: Improve American's access to health care and expand choices of care and service options. Strengthen and expand the healthcare workforce.* (Provider Status)
  - *Objective 2.2: Prevent, treat, and control communicable diseases and chronic conditions.* (Enhanced MTM Pilot Participation)

Pharmacies. The face of neighborhood healthcare.

FDA Update

- Regulatory Reform RFI – comments due 12/7/17
  - Is regulation still current, or is it outdated or unnecessary?
  - Have regulated entities had difficulties complying with regulation?
  - Does regulation impose requirements that are also provided for in voluntary or consensus standards or guidance by third-party organizations?
  - Does regulation contain redundant, outdated, or unnecessary collections of information or retention of records (e.g., reporting, recordkeeping, or labeling requirements)?
  - Could goal of regulation be achieved by less costly means that would provide same level of public health protection?
  - What factors should FDA consider in selecting and prioritizing regulations and reporting requirements for reform?

Pharmacies. The face of neighborhood healthcare.

NACDS

Conclusion and Wrap Up

Pharmacies. The face of neighborhood healthcare.

NON-RESPONSIVE DOCUMENT

Model State Legislation - 7 Day Supply Limits for Opioid Prescriptions for Acute Pain

Prescribing limits for opioid prescriptions issued for acute pain

(1) A practitioner who is licensed under State law to prescribe controlled substances shall not prescribe any schedule II, III, or IV opioid, other than an opioid prescription described in paragraph (3), for the initial treatment of acute pain in an amount in that exceeds a 7-day supply and for which no refill is allowed.

(2) (A) The term "acute pain" means pain with abrupt onset and caused by an injury or other process that is not ongoing.

(B) Acute pain does not include:

(i) chronic pain;

(ii) pain being treated as part of cancer care;

(iii) pain being treated as part of hospice or other end-of-life care; or

(iv) pain being treated as part of palliative care.

(3) An opioid prescription shall not be subject to the limits in paragraph (1) in the following circumstances:

(A) the prescription is for a schedule II, III, or IV opioid drug approved by the Food and Drug Administration for an indication for the treatment of addiction; and

(B) the prescription was issued by the practitioner for the treatment of addiction.

Pharmacists / pharmacies not required to enforce practitioner prescribing limits for opioid prescriptions issued for acute pain

OPTION 1:

(4) A licensed pharmacist or pharmacy who:

(A) dispenses a schedule II, III, or IV opioid pursuant to an otherwise valid prescription, shall be immune from any civil or criminal liability, or disciplinary action from the Board of Pharmacy, for dispensing any schedule II, III, or IV opioid in excess of the limit established in paragraph (1); or

(B) refuses to dispense medications pursuant to a prescription for a schedule II, III, or IV opioid, shall be immune from any civil or criminal liability that might otherwise result from refusing to dispense any schedule II, III, or IV opioid in excess of the limit established in paragraph (1).

OPTION 2:

(4) Pharmacists and pharmacies shall not be subject to disciplinary action or other civil or criminal liability of any kind for dispensing or refusing to dispense medications pursuant to an otherwise valid prescription that exceeds the prescribing limits established by paragraph (1).

Pre-authorization responsibilities with respect to 7-day supply limits for opioid prescriptions issued for acute pain

(5) If an individual or group health plan implements a prior authorization requirement or another policy consistent with paragraph (1), the prescribing practitioner or his/her immediate staff shall utilize health plan processes to complete any required prior authorization prior to issuing the prescription.

7-Day supply limits not subject to Medicaid policies that otherwise limit the monthly number of covered prescriptions.

(6) An opioid prescription issued for acute pain in accordance with paragraph (1) may be filled during the same month without counting against the Medicaid monthly prescription coverage limit.

October 2017

DRAFT

Drug Disposal Model State Legislation

Sec. 1. Drug Disposal Programs

(a) Definitions

1. For purposes of this Section, "retail pharmacy" means a pharmacy that provides services to the public on an outpatient basis.

(b) Pharmaceutical manufacturers whose opioid drugs are sold or distributed within the state shall fund**[, through a stewardship organization,]** and provide at no cost to retail pharmacies, upon request by a pharmacy in quantities to meet anticipated needs as determined by the pharmacy, drug disposal or mail-back envelopes, or other similar consumer-based drug disposal items that retail pharmacies shall provide to retail pharmacy customers, upon customer request, when such a pharmacy customer fills an opioid prescription. Pharmacies shall provide one envelope or item, referenced above, per filled opioid prescription upon request by a pharmacy customer that receives the filled opioid prescription.

Comment [KN1]: Note to PC for consideration: We propose expanding beyond mail-back envelopes.

(c) Pharmaceutical manufacturers whose opioid drugs are sold or distributed within the state shall fund**[, through a stewardship organization,]** the collection of and destruction of mail-back contents or other consumer based contents from disposal items referenced above.

Sec. 2. Consumer Education

(a) The Department **[or a pharmaceutical stewardship organization]** shall fund, develop, and distribute drug disposal educational materials to consumers. The

October 2017

Department **[or stewardship organization]** shall provide the educational materials upon request to retail pharmacies for distribution to customers who fill prescriptions for controlled substances in formats requested by retail pharmacies. Retail pharmacies shall determine the method and mode of distribution of the educational materials, including posting on a pharmacy website or dissemination in electronic format.

(b) The Department **[or stewardship organization]** shall make consumer drug disposal educational materials available on its website.

Sec. 3. Drug Disposal Options

(a) Nothing herein shall prohibit consumers, retail pharmacies or pharmaceutical manufacturers from disposing unused prescription and non-prescription medications in any manner or using any method authorized by law.

Sec. 4. Preemption

(a) This Section preempts any existing or future local laws or ordinances that are contrary to the requirements of this Section or impose more restrictive requirements on retail pharmacies.

October 2017

NON-RESPONSIVE DOCUMENT

NON-RESPONSIVE DOCUMENT

NON-RESPONSIVE DOCUMENT

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Potential Policy Issues Survey – 2018

Please respond via the online survey response tool by October 20 at 12 noon EDT.

NACDS operates with a keen focus on areas of value to members, especially with respect to government advocacy and communicating the story and value of pharmacy. NACDS focuses on the aspects of these priorities that are most valuable to members. Issue prioritization is necessary to promote efficiency and cost-effectiveness and to maximize our prospects for success.

Currently, NACDS is developing its 2018 strategic plan and budget, which ultimately will be considered and approved by the NACDS Board of Directors. As part of this process, the NACDS Policy Council recommends priorities for the Board of Directors.

Instructions

Please work with appropriate personnel within your company to consider and evaluate the relative importance of the issues described in this survey. Each issue is described by topical summaries and/or issue examples. "Federal Issues" and "State Issues" are to be ranked separately. Therefore, please rank the "Federal Issues" in order of importance from "1" to "20," *with "1" indicating the most important issue area* from your company's perspective, and rank the "State Issues" from "1" to "18". The results of the survey will be shared back with the Policy Council for discussion. Please respond via the online survey tool.

The Policy Council will also serve as the forum to bring up additional issues that may come forward during the year and will hold necessary discussions to determine if additions or deletions to the 2018 policy issues should be recommended to the Board.

Please rank the following "Federal Issues" from 1 to 20, with "1" indicating the most important issue area among "Federal Issues" from your company's perspective. Please respond via the online survey tool.

340B Program

NACDS would monitor possible Congressional and Executive Branch action on the 340B program that may negatively impact pharmacy reimbursement or contract pharmacy participation in the 340B program.

Consumer Written Information/Consumer Safety

This category encompasses the various methods used by the federal government (e.g., FDA) to ensure consumers are informed about prescription medications and are using and obtaining them safely. Topics include written

information provided to consumers along with their prescription drugs, such as MedGuides and package inserts; restricted distribution programs such as iPledge and risk evaluation and mitigation strategies (REMS); the regulation of pharmacy compounding; as well as attempts to regulate the sale of prescription drugs via the Internet.

DEA/Prescription Opioid Abuse
Issues under the jurisdiction of the Drug Enforcement Administration (DEA) are included in this category, which covers legislation and regulations pertaining to prescribing limits on opioid prescriptions issued for acute pain and prescription drug monitoring systems. Additionally, this category includes other approaches to combat prescription drug abuse; federal regulation of pharmacies regarding ordering, acquisition, storage, warehousing, distribution, recordkeeping, theft, and loss; dispensing/selling controlled substances, pseudoephedrine, and dextromethorphan; and logbooks.

Drug Disposal
This category covers prescription drug and medical sharps take-back and disposal programs and federal efforts to mandate that pharmacies fund and/or participate in such programs. NACDS believes that a variety of options for drug disposal best meets patient needs. NACDS also supports consumer education programs on drug disposal developed and funded by government and/or pharmaceutical manufacturers.

Electronic Prescribing
NACDS will pursue legislation to mandate that prescribers issue electronic prescriptions for prescription drugs that are covered under Medicare Part D, which will foster prescriber adoption of e-prescribing practices and lead to broader utilization of this technology.

Fraud, Waste, and Abuse
Efforts to reduce fraud, waste, and abuse (FWA) in public programs will continue to be an area of focus for NACDS, particularly as the federal government seeks ways to cut costs. Programs aimed at reducing FWA have resulted in onerous requirements for pharmacies and have significantly increased retail pharmacies' exposure to audits. Examples of these issues include accreditation and surety bond requirements for Medicare Part B durable medical equipment providers, Medicare recovery audit contractors, Comprehensive Error Rate Testing (CERT) audits, Medicaid Integrity Program contractors, and FWA training requirements.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Potential Policy Issues Survey – 2018

Please respond via the online survey response tool by October 20 at 12 noon EDT.

Generic Drug Issues

To keep healthcare costs to a minimum, it is important that there be the availability of interchangeable generic products. NACDS supports policies that allow generic manufacturers to bring products to market as expeditiously as possible and that such products be freely available in the marketplace, with minimal regulatory burdens.

Hazardous Waste

This category covers the formulation of new federal hazardous waste regulations addressing hazardous waste generator status and the handling of pharmaceutical hazardous waste.

Healthcare Connectivity

Medicare has, to some extent, set the standards for telehealth reimbursement. Currently, pharmacies and pharmacists are not recognized providers under Medicare for telehealth reimbursement. In addition to seeking pharmacist provider status for telehealth services, NACDS would support federal telehealth legislation, such as allowing providers to deliver telehealth services across state lines and pursuing pharmacies as medical facilities for telehealth services.

Medicaid

The primary federal Medicaid issue for NACDS is the change to cost-based reimbursement with increased dispensing fees, including issues about average manufacturer price (AMP) based pharmacy reimbursement for generic drugs as a result of the Covered Outpatient Drugs Final Rule. This issue remains a top priority for NACDS and receives significant resources.

Medicare Parts B and D

Medicare Part B issues focus on reimbursement, such as changes to the supplying fee, payment for specialty and biosimilar drugs, as well as other programmatic changes such as the move towards value-based payment systems.

NACDS' work on Medicare Part D covers a wide range of issues, such as the use of fees by Part D plans, the Enhanced MTM pilot being tested by the Innovation Center, and continued beneficiary access to pharmacies. NACDS also comments annually on proposed Part D rule changes and the CMS Call Letter, which advises Medicare Part D plans on requirements for the coming plan year.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Potential Policy Issues Survey – 2018

Please respond via the online survey response tool by October 20 at 12 noon EDT.

Nondiscrimination in Healthcare

NACDS would work with the HHS Office for Civil Rights to clarify the mandates of the ACA Nondiscrimination in Healthcare Final Rule and relieve regulatory burdens imposed by that rule.

PBM, Exchange Issues, and Medicaid Managed Care

NACDS has developed model legislation for the regulation of PBM practices. The NACDS PBM Task Force continues to review and modify this model legislation. However, potential issues in this category include DIR Fees, PBM audits of pharmacies, PBM pricing issues such as MAC and generic predictability, pharmacy network issues, transparency between PBMs and payors, PBM treatment of patient data, and the ability of retail pharmacies to provide 90-day supplies. NACDS monitors and comments on network adequacy and drug benefit designs in exchange plans. This issue area also includes the shift to Medicaid Managed Care.

Prescription Drug Pricing

Policymakers are considering numerous policies to address recent spikes in the prices of prescription drugs. This category includes any federal legislation, regulation or other policy proposals that would affect pharmacy, directly or indirectly, in the debate about prescription drug price inflation, including proposals that would allow importation of prescription drugs from abroad.

Privacy/HIT

In this issue area, we focus on efforts to ensure that pharmacies can continue to receive and transmit electronic prescription transactions with minimal burdens to enhance pharmacy's utilization of this technology and to foster prescriber adoption. Additionally, we work to ensure that pharmacy influences the creation and adoption of electronic health records. For privacy issues, we advocate on issues related to federal HIPAA/HITECH privacy rules and to ensure that pharmacies are not impacted by additional regulation or legislation. We also assist with compliance efforts with existing federal HIPAA rules.

Provider Status for Pharmacists/Pharmacies

With the exception of TRICARE, no federal program recognizes pharmacists or pharmacies as healthcare providers. The lack of this recognition has created issues in the ability for pharmacists to be paid to provide professional services. NACDS is engaging in advocacy efforts to recognize pharmacists as providers in Medicare to facilitate payment for pharmacist-delivered services.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Potential Policy Issues Survey – 2018
Please respond via the online survey response tool
by October 20 at 12 noon EDT.

Specialty Pharmacy
Specialty pharmacy is expanding, and major concerns will be adequate reimbursement and dispensing fees for specialty drugs and the availability of biosimilar medications. Establishing a regulatory pathway that facilitates timely approval of biologics and interchangeable biosimilars, including biosimilar naming issues, are important specialty pharmacy issues. In addition, limited distribution programs developed by manufacturers and approved by FDA may lead to patient access issues.

Supply Chain
This category covers the issues related to implementation of the DSCSA, including, but not limited to, serialization of drug products, wholesaler licensure standards, and development of an electronic interoperable data exchange for drug products.

TRICARE
There continues to be concern that the need for cost saving proposals in defense spending will target the TRICARE program, with specific regard to prescription drugs. In the past couple of years, we have seen increases in copays as well as a movement of brand name maintenance medications to mail order and military treatment facilities. While combating further cuts impacting retail pharmacies, NACDS continues to pursue other solutions that will maintain beneficiary access to retail pharmacies while also helping reduce program costs, including a pilot program for acquisition cost parity.

Value Based Payment Models (VBP)
NACDS supports the goals of VBP models that align performance and health outcomes with compensation by assessing performance using quality and health metrics and provide tools and programs to improve patient health outcomes, enhance care coordination, and create more system efficiencies. With respect to federal programs, NACDS advocates that pharmacists are able to provide the greatest value to patients and reimburse pharmacies accordingly for the innovative services provided by community pharmacists.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Potential Policy Issues Survey – 2018
Please respond via the online survey response tool
by October 20 at 12 noon EDT.

STATE ISSUES

Please rank the following "State Issues" from 1 to 18 with "1" indicating the most important issue area among "State Issues" from your company's perspective. Please respond via the online survey tool.

Consumer Drug Safety Initiatives
This section encompasses efforts in the states related to consumer drug safety. These initiatives include patient counseling, prescription labeling such as patient centered labels, and translation of prescription information (e.g., container labels and patient information). It also covers pharmacy third class of drugs, continuous quality improvement programs and initiatives, and error reporting. NACDS has regularly been involved with these issues to formulate rational approaches in the states.

Drug Disposal
This category covers prescription drug and medical sharps take-back and disposal programs and state efforts to mandate that pharmacies fund and/or participate in such programs. NACDS believes that a variety of options for drug disposal best meets patient needs and supports funding by manufacturers for disposal envelopes at a patient's request. NACDS also supports consumer education programs on drug disposal developed and funded by government and/or pharmaceutical manufacturers.

Electronic Prescribing
NACDS will pursue policies to mandate e-prescribing of all prescription drugs across the states to enhance pharmacy's utilization of this technology and to foster prescriber adoption.

Hazardous Waste
This category includes the state regulation of hazardous waste, including pharmaceutical hazardous waste. Also included here is USP Chapter 800 and state board of pharmacy initiatives to adopt USP Chapter 800.

Healthcare Connectivity
Generally, states are much more generous with reimbursement under Medicaid for telehealth services than Medicare. NACDS supports expanding telehealth access via supporting legislative and regulatory efforts in the states, including greater access under state Medicaid laws and regulations.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Potential Policy Issues Survey – 2018

Please respond via the online survey response tool by October 20 at 12 noon EDT.

Medicaid Managed Care

As Medicaid is increasingly shifting to Managed Care, NACDS plays a role in monitoring states currently moving to managed care including review of RFPs for inclusion of pharmacy-friendly terms such as minimum reimbursement or reimbursement tied to FFS rates. Additionally, in states with already established Managed Care programs, NACDS will work with members to identify approaches to improve the current operating climate and facilitate interactions with state Medicaid agencies where appropriate.

Medicaid & Other State Programs

NACDS devotes significant time and resources to state Medicaid issues. It has been our top issue at the state level, especially concerning full implementation of the CMS Covered Outpatient Drugs Final Rule and movement to cost-based reimbursement. It encompasses all items that impact pharmacy reimbursement – product reimbursement changes, dispensing fees, copayment changes, uncollected copayments, specialty drugs, MAC adjustments, competitive bidding of generics proposals, MFN-based reimbursement, as well as state cost savings initiatives, such as implementation or changes to preferred drug lists or prior authorization requirements, and payment for services (e.g., immunizations). We also work on similar issues for worker's compensation and state employee programs, where appropriate.

Nondiscrimination in Healthcare

NACDS would monitor state legislation and regulations to ensure that state civil rights laws and regulations align with the ACA Nondiscrimination in Healthcare provision.

PBM Issues and Specialty Pharmacy

NACDS has developed model legislation for the regulation of PBM practices. The NACDS PBM Task Force continues to review and modify this model legislation. However, potential issues in this category include DIR Fees, PBM audits of pharmacies, PBM pricing issues such as MAC and generic predictability, pharmacy network issues, transparency between PBMs and payors, PBM treatment of patient data, the ability to provide 90-day supplies by retail pharmacies, and pharmacy discount cards. This issue area also includes the medication synchronization, and concerns about patient access to medications that payers may define as "specialty."

Pharmacist Workload

Pharmacist workload requirements issues include limits on the number of prescriptions that pharmacists may fill; limits on the hours that pharmacists can work, mandatory meal/break periods, and limits on the number of pharmacies a

supervising pharmacist or PIC can oversee. These issues are regulated by state boards of pharmacy.

Pharmacy Automation
Pharmacy automation includes topics such as the use of robotics and automated dispensing systems. NACDS advocates that if boards of pharmacy regulate automated dispensing systems, the regulations should be enabling and flexible and should minimize the administrative burdens so as to not outweigh the benefits of such technological advances.

Pharmacy Technicians
NACDS will continue to advocate that instead of arbitrary ratios, pharmacies should be permitted to determine the appropriate number of pharmacy technicians for the particular community pharmacy site. In addition, we will continue to advocate that Boards of Pharmacy should allow for training options that are best suited to each pharmacy's individual practice setting, such as board-approved employer-based training programs, and that certification of technicians should be voluntary and recognized as one possible method of assessment along with other assessment tools. In addition, certified pharmacy technicians should be permitted to perform additional duties.

NACDS will begin pursuing enhanced tasks for pharmacy technicians including: accepting a verbal prescription, transferring a prescription, consulting with a prescriber for clarifications, final verification of a prescription, checking the prescription monitoring program, performing basic physical assessments, conducting medication reconciliation, administering vaccines, and administering CLIA-waived tests.

Prescription Opioid Abuse
Issues pertaining to combating prescription opioid abuse and diversion are included here. This category includes prescribing limits on opioid prescriptions issued for acute pain as well as broader prescribing and dispensing practices for controlled substances, prescription monitoring program changes, moving pseudoephedrine products to legend drug status, mandating electronic logbooks to track and report the sales of pseudoephedrine products, and requiring positive identification for controlled substance prescriptions.

Privacy/HIT
This category includes work to amend state laws and regulations to allow pharmacies to maintain prescription records in an electronic format only. NACDS also opposes state legislation that gives physicians privacy rights over their

prescribing data. Such legislation prevents pharmacies from disclosing prescriber information.

Specialty and Generic Drug Issues/Biosimilars
Generic drug issues include those that directly affect if and how pharmacists can engage in generic substitution under each state's laws, including interchangeable biosimilars. These issues include state generic substitution requirements in general (i.e., prescription format requirements, patient notification, etc.); special requirements for the generic substitution of certain classes of drugs (i.e., anticonvulsants, immunosuppressant drugs, and interchangeable biosimilars); state defined "narrow therapeutic index" drug lists or formularies and any corresponding requirements; and requirements to pass along all savings to consumers or other payers when a generic drug is substituted for a brand.

Supply Chain
This category covers prescription drug importation, counterfeit drugs, drug returns to wholesalers and reverse distributors, and alignment of state laws and regulations with the provisions of the federal DSCSA.

Value-Based Payment Models (VBP)
NACDS supports the goals of VBP models that align performance and health outcomes with compensation by assessing performance using quality and health metrics and provide tools and programs to improve patient health outcomes, enhance care coordination, and create more system efficiencies. NACDS advocates that pharmacists are able to provide the greatest value to patients and reimburse pharmacies accordingly for the innovative services provided by community pharmacists to the extent that pharmacists are allowed to provide those services under state law.

Value of Pharmacy/Scope of Practice
To coordinate with federal efforts to obtain pharmacist provider status under Medicare Part B, NACDS engages in advocacy to expand pharmacists' scope of practice to be reimbursed for pharmacist-delivered services. These efforts have been focused on removing restrictions for collaborative practice and CLIA-waived tests, expanding pharmacists' immunization authority, expanding pharmacists' authority to furnish certain medications, expanding pharmacists' authority to administer injectable medications, and pursuing waivers to current scope of practice restrictions for innovative research pilots. Other legislative and regulatory actions include medication adherence initiatives, such as MTM, as well as additional authorities for pharmacists, such as independent authority for pharmacists to fill a 90-day supply of non-controlled medications and limited "refill" authority of expired, non-controlled prescriptions by pharmacists.